OPERATOR'S MANUAL

VER2.0C21

Fingertip Pulse Oximeter

Model #: 01MN1000

CE 0120

General Description

Hemoglobin saturation is a measurement of the number of oxygen molecules bound by each molecule of hemoglobin expressed as a percentage. It is a very important physiological parameter for the respiratory/circulatory system. Many respiratory diseases can result in hemoglobin saturation being lowered in human blood. Moreover, the following factors can also lead to problems in oxygen supply, so that human hemoglobin saturation might be reduced: Automatic Organic Regulation Malfunction caused by Anesthesia, Postoperative Trauma, injury caused by some medical examinations, illnesses etc. and may endanger the patient's life. Therefore, it is very important to know the Hemoglobin saturation of the patient so that problems can be identified and rectified in a timely manner.
The Fingertip Pulse Oximeter is a small device with a low power consumption, simple to operate and extremely portable. It is only necessary to apply the device to the patient's finger for the fingertip photoelectric sensor to measure and display the measured value of hemoglobin saturation on the OLED screen. It has been proven in clinical experiments that it is a precise and repeatable method of obtaining the patient's hemoglobin saturation.

Measurement principle

Principle of the oximeter is as follows: An experience formula of data process is established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin(R Hb) and Oxyhemoglobin (O2 Hb) in glow and near-infrared zones. The operating principle of the instrument is Photoelectric Oxyhemoglobin Inspection Technology which is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (660nm glow and 940nm near infrared light) can be focused onto the human nail tip through clamp-type finger sensor. Then the measured signal can be obtained by a photosensitive element, information acquired through which will be shown on two groups of LEDs on the display.

Diagram of Operation Principle

1. **Red and Infrared-ray Emitter Tube**
2. **Red and Infrared-ray Receiver Tube**

Precautions for use

1 Before use, carefully read the manual.
2 Do not use the pulse oximeter in an MRI or CT environment
3 Do not use the pulse oximeter in situations where alarms are required. The device has no alarms.
4 Explosion hazard: Do not use the pulse oximeter in an explosive atmosphere.
5 The pulse oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
6 Check the pulse oximeter sensor application site *frequently* to determine the positioning of the sensor and circulation and skin sensitivity of the patient.
7 Do not use adhesive tape to secure the pulse oximeter sensor to the patient. This may cause inaccurate readings or skin blisters.
8 The pulse oximeter has no SpO2 alarms. It is not for continuous monitoring as indicated by the symbol
9 Prolonged use, or the patient's condition, may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours.
10 Do not autoclave, ethylene oxide sterilize, or immersing the sensors in liquids.

The following may cause inaccurate readings:

Significant levels of dysfunctional hemoglobins (such as carbonxy- hemoglobin or methemoglobin)..
Intravascular dyes such as indocyanine green or methylene blue.
SpO2 measurements may be adversely affected in the presence of high ambient light or direct sunlight (shield the sensor area and, if necessary cover the sensor).
Excessive patient movement or venous pulsations.
Placement of the sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
If the patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia
If the patient is in cardiac arrest or is in shock
Fingernail polish or false fingernails may cause inaccurate SpO2 readings.

Product Properties

1 Operation of the product is simple and convenient
2 The product is small, lightweight (total weight is about 50g including batteries) and convenient to carry.
3 Power consumption of the product is low and the two originally-equipped two AAA batteries can be operated continuously for 30 hours.
4 Low voltage warning will be indicated in visual window when battery voltage is so low that normal operation of the oximeter might be influenced.
5 The product will automatically be powered off when no signal is detected by the product for longer than 8 seconds.

Product Operation Scope

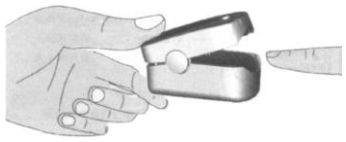
The fingertip Oximeter can be used to measure Hemoglobin Saturation and heart rate through the finger tip. The product is suitable for use in the home, in the field and in hospital (including clinical use in internist/surgery, Anesthesia, pediatrics, intensive care and etc.) and anywhere the measurement of hemoglobin saturation is required.

The product is not suitable to monitor the patient continuously.

Operation Instructions

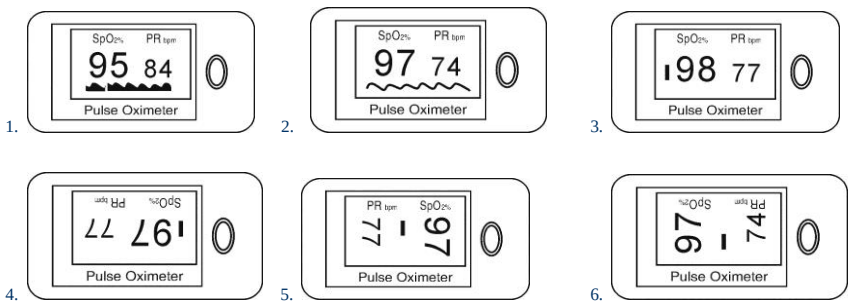
1 Install the two AAA batteries into battery compartment and replace the cover.
2 Grip the clamp as shown below
3 Insert the patient's finger fully into the Oximeter and release the clamp.
4 Press the ON button on front panel once.
5 Read the data from display screen.

Note: When your finger is placed into the Oximeter, the nail surface must be facing upward.



Display Modes

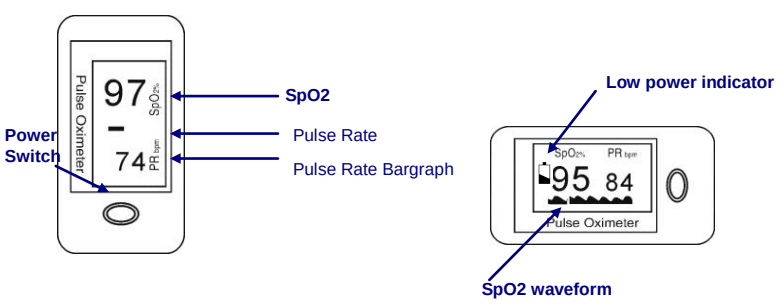
The Oximeter has six (6) display modes. After the Oximeter is turned ON, each time you press the power switch, the oximeter will switch to another display mode as follows:



When you press the power switch for more than one second, the brightness of the oximeter will be changed by degrees, there are 10 levels of brightness; the default level is level four.

Note: Please use medical grade alcohol to clean the rubber inside of the Oximeter between patients and clean the test finger using alcohol before and after each test. (The rubber used is of a medical grade and has no toxins and is not harmful to the skin).

Brief Description of Front Panel



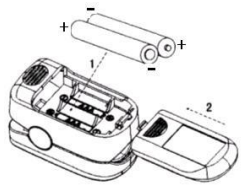
Note: The heart rate bargraph display corresponds with the pulse rate.

Items included

1. Finger Tip Pulse Oximeter – Qty 1
2. Lanyard - Qty 1
3. Batteries 1.5V "AAA" – Qty. 2
4. Carrying case – Qty 1
5. User manual – Qty 1

Battery Installation

1. Install the two AAA batteries into battery compartment. Observe the correct polarity as shown on the device.
2. Push the battery cover horizontally along the arrow shown as below:



Notes: Please remove the batteries if the Oximeter is not to be used for a long time.

Lanyard Installation

1. Thread the thinner end of the lanyard through the lanyard hole.
2. Thread the thicker end of the lanyard through the threaded thinner end and pull tight.

Maintenance and Storage

1. Replace the batteries immediately when the low voltage lamp is lit.
2. Clean surface of the fingertip oximeter before it is used.
3. Remove the batteries inside the battery compartment if the Oximeter will not be operated for a long time.
4. It is best to store the product in ambient temperatures –10 - +40℃ (14 - +104℉) and humidity is 10%-80%
5. It is recommended that the product should be kept in a dry environment.. A wet ambient environment may affect its lifetime and may damage the product.
6. Follow local laws and recycling instructions regarding disposal or recycling of the device and device components, including batteries.

Detailed descriptions of product functions:

1. Display Type: OLED display

2. SpO2:
Measurement range: 70-99%
Accuracy：±2% on the stage of 80%-99%; ±3% on the stage of 70%-80%;

3. Pulse Rate:
Measure range：30-235 BPM
Accuracy：±2 BPM or ±2%（larger）
Pulse Intensity: Bargraph Indicator

4. Power Requirements:
Two AAA alkaline Batteries.
Power consumption: Less than 40mA
Battery Life:
Two AAA 1.5V, 600mAh alkaline batteries up to 30 hours.
Low power indication:

5. Dimensions:
Length: 58mm
Width: 32mm
Height: 34mm
Weight: 50g (including two AAA batteries)

6. Environment Requirements:
Operation Temperature: 5-40℃
Storage Temperature: -10-40℃
Ambient Temperature: 15%-80% in operation
10%-80% in storage

7. Declaration:
EMC of this product comply with IEC60601-1-2 standard
The materials which user can come into contact with are non-toxic and have no affect on body on tissues. The device and materials of manufacture comply with ISO10993-1,-5,-10.

8. Interference Resistance Capacity against Ambient Light: Device works normally in mixed noise produced by BIO-TEK INDEX Pulse Oximeter tester.

Guidance and manufacture's declaration – electromagnetic emissions- for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic emission

The *Pulse Oximeter* is intended for use in the electromagnetic environment specified below. The customer of the user of the *Pulse Oximeter* should assure that it is used in such and environment.

Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The *Pulse Oximeter* uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The *Pulse Oximeter* is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Trouble Shooting Chart

Problems	Possible reason	Solution
SpO2 or PR cannot be read	1. Finger is not inserted correctly 2. Patient's Oxyhemoglobin value is too low to be measured	1. Re-insert finger ensuring that the nail is upwards 2. If the problem persists contact the manufacturer and use an alternate method of measuring SpO2
SpO2 or PR is shown unstably	1. Finger might not be inserted fully 2. Finger is trembling or patient's body is moving	1. Retry by plugging the finger 2. Try not to move
The Oximeter can not be powered on	1. Device will not turn ON 2. Battery power may be inadequate 3. Batteries may not be installed 4. Batteries may be installed incorrectly 5. The Oximeter may be damaged	1. Re-insert finger ensuring that the nail is upwards 2. Replace the batteries 3. Insert the batteries 4. Replace the batteries 5. If the problem persists contact the manufacturer
Indication lamps are suddenly off	1. The product is automatically powered off when no signal is detected longer than 8 seconds 2. Power level of the batteries low	1. Normal 2. Replace the batteries
"Error3" or "Error4" Displayed on screen	1 .Low power 2. Receiving tube being shielded or damaged together with broken connector. 3. Mechanical Misplace for receive-emission tube 4. Amp circuit malfunction.	1. Replace the batteries 2. Contact the manufacturer 3. Contact the manufacturer 4. Contact the manufacturer
"Error7" displayed on screen	1. Low power 2. Emission tube damaged. 3. Current control circuit malfunction.	1 Replace the batteries 2 Contact the manufacturer 3 Contact the manufacturer

Symbol Definitions

Symbol	Definition
	The equipment type is BF
	Refer to user manual before application
SpO_2%	Hemoglobin saturation
BPM	Heart rate (BPM)
	Low power indication
SN	Serial No.
SpO_2	Not for continuous monitoring
IPX1	Drip－proof
REF	Model No.

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